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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,430	09/22/2003	John F. Shanley	032304-055	2375

43027 7590 04/05/2007  
CINDY A. LYNCH  
CONOR MEDSYSTEMS, INC.  
1003 HAMILTON COURT  
MENLO PARK, CA 94025

EXAMINER
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ANDERSEN, MICHAEL T

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

<b>Office Action Summary</b>	<b>Application No.</b> 10/668,430	<b>Applicant(s)</b> SHANLEY, JOHN F.	
	<b>Examiner</b> M. Thomas Andersen	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 29,30 and 36-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28,31-35 and 41-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 10/23/2003, 8/09/2004, 12/12/2006.

## **DETAILED ACTION**

### ***Priority***

Acknowledgement is made of the claim to benefit of provisional application number 60/412,489, filed on 09/20/2002.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) received on 10/23/2003, 08/09/2004, and 12/12/2006 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, 31-35, and 41-52, directed to a stent with a beneficial agent and related method of using.

II. Claims 29-30 and 36-40 directed to a process of making a stent with a beneficial agent.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the stent with beneficial agent can be made by a materially different process, e.g. one not using a piezo-electric micro-jet.

During a telephone conversation with Cindy Lynch on March 30, 2007 a provisional election was made without traverse to prosecute the invention of a stent with a beneficial agent, claims 1-28, 31-35, and 41-52. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-30 and 36-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 recites the limitation "the second beneficial agent" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4-5, 10, 15-18, 20, 23-26, 28, 31-35, 41, 44-45, 50-52 are rejected under 35 U.S.C. 102(a) as being anticipated by Hossainy, U.S. 6,558,733.

Hossainy discloses a stent having a plurality of openings filled with beneficial agents. Specifically, Hossainy discloses a cylindrical device which is expandable, a first plurality of openings containing a first beneficial agent on first and second ends of the cylindrical device; a second plurality of openings containing a second beneficial agent

positioned on a central portion of the cylindrical device, wherein the second beneficial agent can be different than the first beneficial agent. See Hossainy, col. 5, lines 28-30.

The beneficial agents can comprise different forms of the same drug. See e.g. Hossainy, col. 4, line 41 – col. 5, line 19.

The lumen of the stent is considered the side hole (Applicant's claim 17). Hossainy further discloses interconnected struts 24 and bridging elements (e.g. 22), and the first and second openings are formed in the struts and bridging elements, respectively or otherwise, depending on which openings are defined as the "first and second" openings. See Fig. 4a.

Hossainy discloses the related method of positioning the device. See col. 3, lines 55-65.

Further, the openings can be different sizes. See col. 5, lines 25-28. The openings can be formed by a laser. See Abstract. The holes can have different shapes. Cf. Figs. 5a-6.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3, 6, 11, 14, 19, 21-22, 27, 42-43, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Vallana et al., U.S. 6,699,281 ("Vallana").

Hossainy does not specifically disclose that the drug itself has a different concentration. However, Vallana discloses that it is well known in the art to implant drugs having different concentrations in a stent. See Vallana, col. 8, lines 15-30; Figs. 10A-10D. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to vary the concentration, and thus the eluting profile, of the agents within the stent openings.

Claims 7-8, 12, and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Welsh et al., U.S. 2005/0278016 ("Welsh").

Hossainy does not specifically disclose coating the stent with a third beneficial agent, nor using paclitaxel. However, Welsh discloses that it is well known in the art to coat the stent with a beneficial agent (¶ 0144), and that paclitaxel is commonly used as a beneficial agent (¶ 0078). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a third beneficial agent on the exterior of the stent, or to use paclitaxel as the first beneficial agent, in view of the teachings of Welsh.

Claims 9, 13, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Schreeder et al., U.S. 2002/0007209 ("Schreeder").

Hossainy does not specifically disclose using rapamycin. However, Schreeder discloses that it is well known in the art to use rapamycin as a beneficial agent (¶ 0152). Therefore, it would have been obvious to one having ordinary skill in the art at the time

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of the invention to use rapamycin as the first beneficial agent, in view of the teachings of Schreeder.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

March 30, 2007



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER